

EXHIBIT 10

Bruce Rosenzweig, M.D.'s Expert Report
Jennifer Ramirez v. Cesar Reyes, et al.

I. Qualifications

For qualifications and a copy of CV, please reference general liability report which was filed in conjunction with this report.

II. Documents Reviewed

In addition to all of the materials reviewed and listed in my general liability report and exhibits, I have reviewed the following case specific documents related to Jennifer Ramirez:

Medical & Billing Records from the following providers:

1. Northeast Baptist Hospital
2. Baptist Health System
3. Urology of San Antonio
4. Stone Oak Urgent Care/Family Practice
5. Stone Oak MRI
6. Walgreens
7. Pasteur Plaza Surgery Center
8. St. Luke's Baptist Hospital
9. Women Partners in OBGYN
10. South Austin Hospital
11. Seton Medical
12. San Antonio Arthritis Care Centers
13. Vicki Rickerson
14. Impact Urgent Care
15. Austin Regional Clinic

16. Institute of Women's Health
17. University of Texas Southwestern Medical Center
18. Pictures from Dr. Zimmern's Office

Depositions and Exhibits

1. Jennifer Ramirez - Deposition Transcript, June 23, 2014 and August 20, 2014
2. Dr. Cesar Reyes - Deposition Transcript, August 14, 2014 and September 20, 2014
3. Dr. Christopher Graham - Deposition Transcript, August 20, 2014
4. Dr. Jane Atkerson - Deposition Transcript, October 2, 2014
5. Dr. David Talley - Deposition Transcript, October 10, 2014
6. Diana Williams - Deposition Transcript, October 3, 2014
7. Dr. Averess Rickerson - Deposition Transcript, September 24, 2014

III. Opinions

In formulating my opinions and preparing this report, I considered the medical records of Jennifer Ramirez, scientific literature, internal Ethicon documents, testimony from Ethicon employees and other witnesses, and my clinical experience in treating stress urinary incontinence in my practice. All opinions I have are to a reasonable degree of medical and scientific certainty. In forming these opinions a broad differential diagnosis was reviewed and considered including Ms. Ramirez's medical history and conditions. I understand discovery is still ongoing in this case and I reserve my right to amend my opinions if further information is provided in any form including, but not limited to, medical records, corporate documents, depositions and the expert reports of both Plaintiff and Defense experts.

A. Medical Background

On July 15, 2010, Jennifer Ramirez (then known as Jennifer Galindo) was a 28 year old female gravida 4 para 3. She had 3 vaginal deliveries and 1 abortion. She was 62" tall and weighed 145 pounds. With the last vaginal delivery, there was a threat of premature labor and Ms. Ramirez had gestational diabetes. Her medical history indicates she had a hysteroscopy-

tubal occlusion, Essure in May of 2008. She did not indicate any known drug allergies and was not taking any medications at that time.

She was seen by Dr. Cesar Reyes on July 15, 2010 for an annual exam and pap smear. Ms. Ramirez complained of sharp, severe pain in her lower abdomen occurring before menses. She also complained of moderate urinary incontinence which she said had been occurring for 2 years which were aggravated by coughing, sneezing, straining and lifting heavy objects. Lastly, she complained of heavy menses over the last 3 years. The assessment and plan was to do a Multistix and Urine Culture/Sensitivity Routine. The impression was first degree cystocele.

On August 2, 2010, she was seen by Dr. Reyes for a sonogram follow up. Stress Urinary Incontinence was noted in the Problem List/Past Medical. The impression was still a first degree cystocele. Ms. Ramirez discussed treatment options for her menorrhagia, fibroids, and SUI and indicated she wanted to proceed with a total laparoscopic hysterectomy and TOT procedure. Ms. Ramirez stated in her deposition that her stress urinary incontinence was only with vigorous cough or sneeze or occasionally while jumping on a trampoline.

On September 13, 2010, Ms. Ramirez was seen prior to her hospital visit for her laparoscopic hysterectomy and TOT procedure. She complained of the same SUI problems at this visit. The assessment was a uterine myoma, menorrhagia, dysmenorrhea, and SUI. She was catheterized for residual, only a few drops were obtained. She was then counseled for her upcoming procedures.

On September 17, 2010, Ms. Ramirez underwent a total laparoscopic hysterectomy and TVT-O. Ms. Ramirez was positioned on the operating table so that her buttock was flush with the edge of the table. During the TVT-O procedure, which was done under general

endotracheal anesthesia, Dr. Reyes noted that appropriate placement was obtained and the plastic sheath was removed from the sling at the exit points. Sharp dissection was described for the TVT-O procedure. The operative report notes that a 9, 10 Hegar dilator was positioned in between the vaginal suburethral incision and the sling. The hysterectomy was performed before the TVT-O procedure. On September 19, 2010, Ms. Ramirez's discharge summary noted an uncomplicated course and she was voiding without difficulty.

On September 27, 2010, Ms. Ramirez presented for a post-operative visit. She indicated she feels well and with no complaints. Dr. Reyes noted the incisions were healing properly, the stitches were removed and the Ms. Ramirez is doing well. Ms. Ramirez had a urine culture which revealed a urinary tract infection. She was prescribed Macrobid for treatment. On October 8, 2010, Ms. Ramirez called Dr. Reyes' office complaining of a urinary tract infections saying she is experiencing urinary pain and frequency. She stated the Macrobid did not help. She was status-post TLH and TVT-O.

Ms. Ramirez called Dr. Reyes' office on November 4, 2010 stating her urine is cloudy again and she was advised she likely has another urinary tract infection. She indicated these infections began after her surgery, that she was very upset, and she would like to follow up with an urologist. On November 15, 2010, she presented for an evaluation of lower urinary tract symptoms and for voiding symptoms to Dr. David Talley. She indicated her urine stream was weak, hesitant, difficult to maintain, and intermittent. She complained of pain with voiding and the 2 urinary tract infections since the hysterectomy and TVT-O. During this office visit, a cystoscopy was performed. The cystoscopy described a normal bladder and urethra. The diagnosis was pelvic pain after BN sling; Dr. Talley could feel the bowstring of the sling. The plan was to obtain her old medical records and he prescribed Valium to relax her pelvic

muscles and ordered a urine culture. She was also instructed to see Dr. Graham to discuss the possible incision of BN sling.

On November 23, 2010, Ms. Ramirez was seen for voiding difficulty by Dr. Christopher Graham. It was noted she was able to void with some difficulty initiating her stream. There was no incontinence and she only had SUI with coughing before surgery. It was also noted that she had some vaginal bleeding after sex or after a bowel movement and had pain on her left side with sex. During the physical exam, the mesh was palpable deep to the left vaginal wall and the entire left side pelvic floor was tender with trigger point at insertion. Dr. Graham diagnosed Ms. Ramirez with dyspareunia and the mesh arm was tight on the left side. The plan was made to try Valium before sex and pelvic floor therapy to release left side of the sling insertion site.

On December 1, 2010 Ms. Ramirez presented with vaginal discharge which had been occurring for 6 days. She also complained of vaginal bleeding. During examination, she was tender in the left inner vaginal wall where mesh was placed. The assessment and plan included a wet prep and Multistix and to follow-up if there was no improvement or if symptoms worsen. Granulation tissue at the vaginal cuff was cauterized at this visit.

Ms. Ramirez was seen by Dr. Graham on December 6, 2010, when she was complaining of pelvic pain and vaginal bleeding. After assessing and diagnosing the pelvic pain, vaginal bleeding, and tight left insertion of TVT-O, a plan was made to conduct a vaginal exploration and revision of the sling. On December 22, 2010, Ms. Ramirez went to the hospital for a partial excision of transobturator tape and excision and fulguration of granulomas at the vaginal cuff. During the procedure, Dr. Christopher Graham was able to feel the left side of the transobturator tape mesh right at its insertion into the obturator muscle. Dr. Graham was able

to excise approximately 1cm of the right at the insertion of the obturator muscle. Dr. Graham's diagnosis was listed as, "PELVIC PAIN FROM TRANSOBTURATOR TAPE, VAGINAL BLEEDING."

On August 30, 2011, Ms. Ramirez presented to Dr. Graham with a chief complaint of leaking urine. She indicated the incontinence had been present for several months. Dr. Graham noted it was urge incontinence. She indicated it began after the excision/revision of the TVT-O and fulguration with excision of vaginal lesion. Dr. Graham found urge urinary incontinence after the excision and poor muscle control. During this visit Dr. Graham was unable to pass a Q-tip through the urethra. The plan was to seek pelvic floor therapy.

On April 9, 2013, Ms. Ramirez presented to Dr. Jane Atkerson reporting dyspareunia occurring with a deep thrust. Ms. Ramirez indicated her dyspareunia had been a problem for two years. Dr. Atkerson recommended Ms. Ramirez see a physical therapist for evaluation of her pelvic floor dysfunction.

On September 18, 2014 Ms. Ramirez was seen by Dr. Vicki Rickerson, Internal Medicine with complaints of vaginal discharge. Ms. Ramirez stated her symptoms began 2 days before and she was experiencing vaginal itching and irritation. She denied fever or dysuria. Dr. Rickerson commented that she had been treated for a UTI 3 – 4 weeks ago and developed a yeast infection after that did not respond to diflucan. Ms. Ramirez volunteered that she had a small amount of mesh protrusion, and that this might be causing an element of the problem. She had attempted to call her gynecologist, but the soonest she could get in was in 4 days.

On July 16, 2014 Ms. Ramirez requested an appointment with Dr. Phillippe Zimmern. The reason for the appointment was to get a second opinion for a mesh implant. She stated she

had constant pain in the vaginal area on the left side and she had had a mesh surgery four years ago.

Ms. Ramirez was seen by Dr. Kathleen Chin at the UT Southwestern Medical Center on November 21, 2014 as a new patient for Dr. Phillippe Zimmern. Ms. Ramirez indicated she was having a constant pain, rated at a level six, in her lower left abdominal region. During the physical examination, Dr. Chin elicited pain in the lower left quadrant, down medial, and the upper aspect of left thigh, and noted left sided vaginal discomfort with gentle palpation in trajectory of the transobturator tape. Dr. Chin's impression of her examination of Ms. Ramirez included pelvic pain, dyspareunia, mild sensory neuropathy and likely obturator involvement from prior TOT. Dr. Chin counseled Ms. Ramirez on the possibility of surgery to remove the mesh tape on the left side.

On January 22, 2015, Ms. Ramirez was seen by Dr. Phillippe Zimmern at the UT Southwestern Medical Center. On cystoscopy Dr. Zimmern found chronic extensive trigonitis and a very tight distal urethra. An X-ray Voiding cystourethrogram on January 22, 2015 showed a maximum cystometric capacity of 450 ml, urinary incontinence with high volume stress, minimal post void residual no cystocele or reflux. On January 26, 2015 she underwent an MRI of the pelvis which showed fibrosis versus sling in the urethrovaginal area, thicker on the left, abutting the left anterior vaginal wall and left puborectalis muscles. On February 2, 2015 a pelvic ultrasound showed linear band of echoes abutting the posterior margin of the urethra between 5:00 and 9:00 position likely arising from residual TOT suburethral sling.

Ms. Ramirez and Dr. Zimmern discussed removing the right side transobturator tape and portion underneath the urethra. Removal surgery was scheduled for March 10, 2015.

On March 9, 2015, Ms. Ramirez had her pre-op visit. Ms. Ramirez reported a history of

chronic pain in the pelvic area for four years affected by activity and movement. She also reported that since her revision she has been having frequency and urgency incontinence, that it feels like the mesh is protruding into her vaginal canal, a constant dull pain and pain shooting down her left leg, described as the antero-medial thigh down to knee and occ down to toes, frequent UTIs and bacterial infections, and dyspareunia on the left side of the inside of the vagina. During the physical exam, performed by Dr. Ilana Jacobs, Dr. Jacobs found pain on the inner side of the left thigh, pain inside the vagina on the left side, tenderness along the course of tape, and extensive trigonitis.

On March 10, 2015, Ms. Ramirez had her removal surgery. The preoperative and postoperative diagnosis was dyspareunia, dysuria, and incomplete bladder emptying. Cystoscopy was performed prior to surgery. The urethra appeared very narrow and compressed with elevation of the floor of the urethra in the mid region. Grade 4 trabeculations were noted as well as squamous metaplasia. There were no areas of infections so no cauterization was performed. Two scars were found on the vaginal wall, one on the right of the midline and one on the left. A short transverse incision was made in the anterior vaginal wall midway between the urethral meatus and bladder neck. The blue weaves of the mesh were identified just of the left side of the urethra around the 4 or 5 o'clock position. Scar tissue was also noted. The edges of the mesh were grasped and the tape was lifted off the floor of the urethra carefully from left to right. The tape was then tracked lateral to the urethra toward the inferior pubic arch. The tape was completely removed until it disappeared behind the pubic arch. Hemostasis was performed. The left side was then explored. The trigone where the tape used to be was identified. Palpation through the obturator internus was done and no further tape remnant was noted on the left side. Another cystoscopy was performed revealing a normal urethra without

distortion. Ms. Ramirez stayed overnight at the hospital and was discharged the next day on March 11, 2015.

On March 11, 2015, the pathology report was signed by Jason A. Mull, M.D. showing that the specimen was received in formalin and consists of two fragments of blue, flexible mesh embedded with friable to partially cauterized soft tissue. The final diagnosis states the synthetic mesh material is embedded with fibrous tissues with chronic inflammation.

C. Opinions

All the opinions that I am offering I hold to a reasonable degree of medical certainty. As discussed in my general liability report, the heavyweight small pore old construction mechanical cut Polypropylene mesh (Prolene) like that contained in the TVT-O device implanted in Ms. Ramirez has many well-known characteristics that should have caused Ethicon to avoid its use in a product intended for permanent implantation into the human vaginal floor. These characteristics, along with the obturator approach used with the TVT-O device, include the following: (1) degradation of the mesh; (2) chronic foreign body reaction, including chronic inflammation in close proximity the obturator nerve bundle and muscles, ; (3) fraying, sharp edges and particle loss; (4) Infections and Bio-films; (5) roping and curling of the mesh; (6) loss of pore size with tension; (7) fibrotic bridging leading to scar plate formation and mesh encapsulation; and (8) shrinkage/contraction of the encapsulated mesh.

As a result, Ethicon's TVT-O mesh (Prolene) is not suitable for its intended application as a permanent prosthetic implant for stress urinary incontinence in women, and Ethicon failed to act as a reasonable and prudent medical device manufacturer by manufacturing and selling its Prolene mesh in a permanent prosthetic implant like TVT-O.

As a result of these and other inadequacies with the mesh, it is my opinion to a reasonable degree of medical certainty that the implantation of the TVT-O device caused Ms. Ramirez to suffer numerous injuries which are permanent in nature. Specifically, the characteristics of the mesh led to the initial bowstring felt by Dr. Talley in 2010 and the chronic inflammation seen in Ms. Ramirez's pathology report from her most recent revision surgery. This chronic inflammation produced and continues to produce the injuries discussed above as well as retroperitoneal, space of Retzius, hematoma, a chronic foreign body reaction and chronic inflammation, encapsulation of the mesh, erosion of the TVT-O mesh, pain, nerve damage and irritation, muscle irritation, dyspareunia, significant bladder issues (discussed above and below) and the need for removal of the remaining mesh. Dr. Zimmern's pre-operative and intra-operative evaluation noted elevation and compression of the mid urethra, the exact location of the midurethral sling. This is indicative of mesh contraction due to scarring from the chronic inflammation seen on the explant pathology report. Mesh contraction, as well as other characteristics of the mesh like roping, curling, particle loss and fraying, are a likely cause of her complaints of vaginal pain, dyspareunia and inner thigh pain. These complaints related to mesh contraction and deformation are especially concerning when the mesh is implanted in close proximity to the obturator nerve bundle as with the TVT-O.

In addition, it is my opinion to a reasonable degree of medical certainty that Ms. Ramirez will have continued and ongoing complications and need additional medical treatments in the future related to the permanent complications she suffered from the inadequacies and implantation of the TVT-O device. Even though much of the sling has been removed, Ms. Ramirez will continue to suffer long term risk of future erosion, pain and continued dyspareunia because the remaining mesh will continue to produce dyspareunia

and a continued risk of erosion. This will mean that she will have the possibility of future erosion, continuing dyspareunia and pain as long as there is sling material left in her pelvis.

Because of these future risks Ms. Ramirez will, more likely than not, need to receive continuous medical care, physical therapy and medications for her pain and dyspareunia. She will also continue to have the risk of future surgery to remove part or all of the remaining TVT-O mesh due to pain, dyspareunia or future erosions. Finally, the treatment that Ms. Ramirez received for the above complications related to the TVT-O was necessitated by the TVT-O.

There were reasonably feasible alternatives available to Ethicon and for the treatment of Ms. Ramirez. For example, the Burch procedure would have been an appropriate treatment for the stress urinary incontinence. As I have testified in the past, the Burch procedure eliminates the risks specifically associated with the old construction heavyweight mesh used in the TVT-O because the Burch procedure does not require the use of mesh. Another feasible alternative to the TVT-O would have included autologous fascia slings.

Moreover, in this case, because of the injuries suffered by Ms. Ramirez, specifically the nerve injuries, groin and thigh pain, and painful revision surgeries, and because of the manufacturing defect present in the mechanical cut mesh Ms. Ramirez received, several additional feasible alternatives were available to Ethicon that would have been less dangerous for Ms. Ramirez. As I have testified in previous cases where women have suffered permanent debilitating injuries from TVT mesh products, these alternatives depend on the patient, patient's lifestyle, patient's medical history, and the injuries the patient suffers from.

In this case, Ms. Ramirez was young and active at the time of her implant. Additionally, the mesh Ms. Ramirez was implanted with contained a manufacturing defect in that the mesh was especially subject to losing particles, fraying and deformation. Because of these factors, and because of the resulting injuries from the TVT-O, certain lighter weight, larger pore mesh resistant to fraying, deformation, shrinkage and particle loss both by design and by improved manufacturing, that would be implanted further away from the obturator nerve bundle and include a less invasive implantation method than that used with the TVT-O would have been less dangerous for Ms. Ramirez.

Ethicon's own internal documents and marketing of laser cut TVT-O mesh also establishes that this would have been a feasible and safer alternative to the mechanically cut TVT-O mesh utilized with Ms. Ramirez. Ethicon's belief that the laser cut mesh was resistant to fraying, roping, curling and particle loss would have reduced the likelihood of mesh particles, frayed mesh, and deformed mesh causing inflammation, pain, and nerve and muscle irritation near the obturator space that Ms. Ramirez now suffers from in this particular case. As I have testified in past cases where women have suffered from life-altering injuries from TVT mesh products, the laser cut mesh used in the TVT products, especially the laser cut mesh used in the TVT-Abbrevio product, is stiff and leads to certain complications in woman. However, the use of a shorter piece of lighter weight mesh resistant to fraying, implanted further away from the obturator nerve bundle because of size of the mesh or implantation method, and implanted in a less invasive manner, would be a product is less prone to lead to the obturator injuries seen with Ms. Ramirez in this case.

Moreover, in this case, the pathology findings and the records associated with Ms. Ramirez's recent removal surgery indicate chronic inflammation from the frayed and

deformed mechanical cut mesh used in Ms. Ramirez, as well as contraction from the heavyweight mesh used in Ms. Ramirez, especially in close proximity to the obturator nerve bundle thereby causing her injuries in this case, make other alternative options available to Ethicon, as described above, less dangerous for Ms. Ramirez.

In addition, based on Ethicon's internal documents, deposition testimony, and the medical literature, feasible alternatives would have included individually or collectively a lighter weight, larger pore mesh material. Indeed, Ethicon had lighter weight larger pore meshes that were less stiff and more compliant with patients' tissues that Ethicon marketed for use in the pelvis. A midurethral sling device which contained a shorter piece of mesh and had arms consisting of suture like material would have also been a safer alternative. And, finally, a midurethral sling device that did not include the invasive obturator approach and placement used with the TVT-O would have been a safer alternative for Ms. Ramirez.

Additionally, I continue to review internal Ethicon documents and the relevant body of medical literature on a continual basis. I also see women with chronic mesh complications on a continual basis. When I evaluate these women, whether it is in my practice or in a litigation setting, I see life-altering injuries that are related to the type of mesh these women were implanted with, the method in which the mesh was implanted, where the mesh was implanted, but also the patient's lifestyle and makeup. In many of these cases, where one option may be less dangerous for a certain patient, in another patient that same option may be more dangerous. This is because of the unique patient specific concerns that pelvic floor surgeons, like myself, encounter on a daily basis when evaluating medical treatment for specific patients. Indeed, Ethicon recognized that certain treatment options may be safer alternatives to other treatment options based on patient specific factors

and specific risk factors associated with the procedure and patient. As more fully described above, because of these and other factors, multiple safer alternatives were feasible at the time of Ms. Ramirez's surgery.

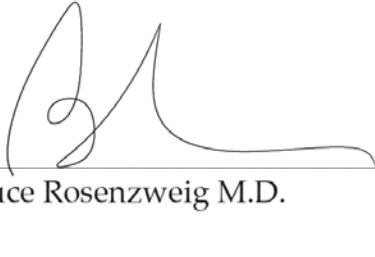
As discussed in my general liability report, Ethicon failed to include significant adverse events and risks in its IFU for TVT-O, including, permanent, lifelong and debilitating pelvic and obturator pain, lifelong sexual complications and dysfunction, urinary problems, worsening incontinence, lifelong risk of multiple surgeries, need for removal of the device, lifelong risk of erosions, and the risk of serious complications and effect on a patient's quality of life. The IFU fails to include the frequency, duration and severity of the risks associated with the device. Moreover, the IFU fails to inform physicians that patients may require multiple surgeries to treat erosions, that erosions could be severe and untreatable, that patients could endure lifelong severe pain or dyspareunia/painful sex, removing the mesh and revision surgeries can be complicated and challenging for both the patient and physician, and complete removal of the TVT-O mesh is likely impossible.

In addition, Ethicon failed to include significant risks in its IFU related to the Prolene polypropylene mesh, including that the mesh can degrade, shrink, deform and contract. The IFU also fails to include additional risks associated with the Prolene mesh, including chronic foreign body reaction, fibrotic bridging, infections/biofilms, fraying/particle loss and roping/curling of the mesh. This is true despite the fact that according to senior regulatory and medical affairs employees at Ethicon, it had knowledge of these risks prior to the launch of the TVT-O.

All opinions I have are to a reasonable degree of medical certainty. I have also

reviewed the opinions of Dr. Erin Carey, Dr. Vladimir Iakovlev and Dr. Michael Margolis and incorporate those opinions herein. I understand discovery is still ongoing in this case and I reserve my right to amend my opinions if further information is provided in any form including, but not limited to corporate documents, depositions and the expert reports of both Plaintiff and Defense experts.

Signed this 24th day of April, 2015.

X 
Bruce Rosenzweig M.D.